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REMARKS

Claims 169-197 are pending in the subject application. Applicants have amended claims 169, 171, 175, and 179.

Applicants maintain that the amendments to the claims raise no issue of new matter. Support for the amendments to claim 169 may be found *inter alia* in the specification as originally filed on page 87, lines 31-35. Applicants respectfully request entry of this Amendment. Upon entry of this Amendment, claims 169-197, as amended, will be pending and under examination.

In view of the remarks which follow, applicants respectfully request that the Examiner reconsider and withdraw the rejections made in the July 30, 2003 Office Action.

Rejection Under 35 USC §112, first paragraph

On page 2 of the July 30, 2003 Office Action, the Examiner rejected claims 169-197 under 35 U.S.C. §112, first paragraph alleging that the specification, while being enabling for compounds as set forth by the exemplified compounds, does not reasonably provide enablement for the biological method of treatment as claimed in claims 169-197. The Examiner further alleged that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate with these claims.

The Examiner alleged that the claims encompass an astronomical number of compounds which have a specific inhibition of a biological pathway without setting forth the compounds exemplified in the specification. The Examiner then stated that

the skilled artisan would not be able to determine which compounds are within the scope of applicants' claims without undue experimentation.

In response to the Examiner's rejection, applicants respectfully traverse for the reasons set forth below.

Applicant notes that the claimed invention is a method of treating an eating disorder or obesity in a subject which comprises administering to the subject a therapeutically effective amount of an MCH1 antagonist or an MCH1 agonist. In this method, the MCH1 antagonist administered inhibits the activation of the MCH1 receptor with an antagonist potency which is at least 10-fold greater than the antagonist potency with which the MCH1 antagonist inhibits the activation of the NPY1 receptor.

The claimed method is based on applicants' surprising invention which provides a valuable treatment for eating disorders and obesity which employs the use of MCH1 antagonist compounds having defined receptor pharmacological properties.

Applicants maintain that the disclosure enables the claimed method. One skilled in the art, based on the disclosure, could practice the claimed method without undue experimentation. Since applicants do not claim compounds used in this method, it is irrelevant whether one skilled in the art could make any specific compound or all such compounds without undue experimentation. The number of exemplifying compounds is extremely large and more than adequately enables the claimed method. Applicants emphasize that it is the specification which much enable the invention not the claim which much do so.

The MCH1 receptor adapted for expression in a cell is described on page 51, line 21-33. Methods for identifying MCH1 receptor antagonists are described on page 114, line 29 through page 128, line 2; and page 367, line 33 through page 369, line 19. Methods for administering a therapeutically effective amount of an MCH1 antagonist to a subject are described on pages 359, lines 5-9; page 360, line 19 through page 361, line 2; page 361, lines 20-21.

Applicants describe how to express the cDNA of various receptors and how to carry out assays in heterologous systems on page 108, line 13 through page 113, line 28; page 375, line 25 through page 376, line 12; and page 95, line 6 through page 98, line 35.

The subject application further describes 114 compounds which are useful in the claimed method. In order to use the subject invention, MCH1 antagonists need not be made, rather they can be compounds which already exist, and which must simply be identified as having the requisite pharmacological properties.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. §112, first paragraph.

Rejection Under 35 U.S.C. §102

The Examiner rejected claims 169-197 under 35 U.S.C. §102(e), as allegedly anticipated by Bruce et al. (5,889,016, hereinafter "Bruce"). The Examiner alleged that Bruce teaches in the abstract (Formula I) and at column 4, line 66 to column 12, line 45, dihydropyrimidinone compounds can be administered to treat eating disorders. The Examiner then alleged that at column 12, lines 34-35 it is taught that dihydropyrimidinone compounds have utility

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in the treatment of food intake disorders, such as obesity, anorexia, bulimia, and metabolic disorders. The Examiner further alleged that the biological pathway as claimed by the applicant in claims 169-197 would be inherent in the administration of the compounds taught by Bruce to treat eating disorders.

In response to the Examiner's rejection, applicants respectfully traverse for the reasons set forth below.

M.P.E.P. §2131 states:

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. . . . The identical invention must be shown in as complete detail as is contained in the . . . claim. . . .

Applicants point out that amended claim 169 recites:

A method of treating an eating disorder or obesity in a subject which comprises administering to the subject a therapeutically effective amount of an MCH1 antagonist which inhibits the activation of the MCH1 receptor with an antagonist potency which is at least 10-fold greater than the antagonist potency with which the MCH1 antagonist inhibits the activation of the NPY1 receptor.

Applicants point out that claim 192 recites:

A method of treating an eating disorder in a subject which comprises administering to the subject a therapeutically effective amount of an MCH1 agonist.

Applicants further point out that the compounds taught by Bruce are described as NPY Y1 antagonists. Applicants maintain that the '016 patent does not teach each and every element of the instant claims.

In fact, contrary to the Examiner's statement, the biological

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pathway recited in applicant's claims 169-197 is not inherent in the administration of the compounds taught by Bruce, because the claims as amended herein teach away from the Bruce compounds which are defined as NPY Y1 antagonists.

Accordingly, applicants maintain that Bruce does not anticipate their claimed invention because Bruce does not disclose a MCH1 antagonist which has lower potency as an NPY Y1 antagonist as defined in their claims. Applicants respectfully request that this ground of rejection be reconsidered and withdrawn.

Rejection under 35 U.S.C. §103

On page 4 of the July 30, 2003 Office Action the Examiner rejected claims 169-197 under 35 U.S.C. §103(a) as allegedly unpatentable over Bruce (supra).

The Examiner alleged that the difference between applicants' claims and Bruce is that the dihydropyrimidinone compounds differ as the phenyl moiety is substituted with the piperazine moiety. The Examiner then alleged that the skilled artisan would be motivated to use the Bruce compounds with a reasonable expectation of success.

MPEP §2143.01 recites:

In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification.

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Applicants respectfully traverse the Examiner's rejection for the following reasons.

Applicant maintains that the instant claims are not obvious over Bruce because Bruce does not provide any teachings or suggestions that one can make changes or modifications to Bruce's exemplified structure and still maintain an effective treatment.

In view of the remarks and amendments made hereinabove, applicants maintain that their invention as now claimed is patentable over Bruce. Applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.